Butler, Jennie C

From: MaryPowers [MaryPowers@goplay.com]
Sent: Tuesday, September 21, 1999 1:17 AM
To: fdadockets@oc.fda.gov
Subject: Egg Labeling/Refrigeration Rules

September 20, 1999

Food and Drug Administration
Department of Health and Human Services
21 CFR Parts 16, 101, and 115
Docket Nos. 98N-1230, 96P-0418, and 97P-0197
Proposed Egg Rules (Labeling and Refrigeration)

The Federal Register notice of July 6, 1999 (Vol. 64, No. 128, p. 36491-36516) concerning these proposed rules states: "FDA believes that it is this transovarian contamination that is responsible for the increased number of SE-related salmonellosis cases described in section I.A. of this document," and "Because studies suggest that infectious dose for SE can be low, FDA believes that the ideal solution to this public health problem would be to adopt measures to eliminate viable SE in shell eggs, either through preventing transovarian and trans-shell contamination...." (ps. 36493-36494). It then goes on to state: "However, FDA has tentatively concluded that eliminating viable SE in shell eggs in either of these two ways is not yet practicable" (p. 36495).

Since Salmonella enteritidis in passed directly from hen to egg, true prevention will require safeguards at this stage in the egg production and processing chain. There are numerous production practices which have long been known or highly suspected of being contributing factors to Salmonella infection and contamination. Such practices as overcrowding these birds, rendering Salmonella-infected chickens into chicken feed, and forced molting hens make Salmonella contamination inevitable. These are widely employed practices which, in addition to deleteriously impacting on the animals' well-being, pose public health hazards. The prohibition of these practices would be very practicable in correcting the problem of Salmonella contamination - which is largely a managment-caused problem. They are also practices which the FDA has the authority to prohibit, and which it has an ethical responsibility to do. A petition for the FDA to prohibit the practice of forced molting has, in fact, been pending with the agency for over a year, and on which it has taken no substantive action.

These practices would be far more effective and efficient than labeling or refrigeration requirements -which are intervention measures, rather than preventive ones- and the agency should make the improvement of production practices top priority. For example, there are far fewer egg production sites than there are distribution and retail sites, and the agency would be better able to monitor and inspect them. To effectively address Salmonella enteritidis infection from eggs, the FDA must focus on preventative measures at the production level.

Most sincerely,

Mary Finelli

8514 Madison Street

New Carrollton, Md., 20784

(301) 459-5192

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EC 7

HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CROSS REFERENCE SHEET

Docket Number/Item Code:	98N-1230/EC7
See Docket Number/Item Code:	97P-0197/EC7 96P-0418/EC7